

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Nobuaki TAKAHASHI et al.  
Title: MUTANTS OF ANTI-CD40 ANTIBODY  
Int'l. Appl. No.: PCT/JP2004/019750  
Int'l. Filing Date: 12/24/2004  
Examiner: Unassigned  
Art Unit: Unassigned  
Confirmation Number: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

AP20 Rec'd PCT/PTO 23 JUN 2006  
TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

**RELEVANCE OF EACH DOCUMENT**

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report are not being submitted herewith.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 23, 2006  
FOLEY & LARDNER LLP  
Customer Number: 22428  
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By Courtesy C. Brinckerhoff  
Courtesy C. Brinckerhoff  
Attorney for Applicant  
Registration No. 37,288

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	Unassigned <b>10/584345</b>
Date Submitted: June 23, 2006		Filing Date	June 23, 2006
(use as many sheets as necessary)		First Named Inventor	Nobuaki TAKAHASHI
Sheet 1 of 2		Group Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	081356-0262

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
			WO 2002/088186	A1	Kirin Brewery Co., Ltd.	11/7/2202		
			JP 2003-519470	A	SEATTLE GENETICS INC.	6/24/2003		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		E.E. IDUSOGIE et al., "Mapping of the Clq binding site on rituxan, a chimeric antibody with a human IgG1 Fc", 2000, J. Immunol., 164(8), p. 4178-4184.	
		M. H. TAO et al., "Structural features of human immunoglobulin G that determine isotype-specific differences in complement activation", 1993, J. Exp. Med., 178(2), pp. 661-667.	
		A. MORGAN et al., "The N-terminal end of the CH2 domain of chimeric human IgG1 anti-HLA-DR is necessary for Clq, Fc gamma RI and Fc gamma RIII binding", 1995, Immunology, 86(2), pp. 319-324.	
		M. P. REDDY, et al., "Elimination of Fc Receptor-Dependent Effector Functions of a Modified IgG4 Monoclonal Antibody to Human CD4", 2000, J. Immunol., 164, pp. 1925-1933.	
		S. ANGAL et al., "A single amino acid substitution abolishes the heterogeneity of chimeric mouse/human (IgG4) antibody", 1993, Mol. Immunol. 30(1), pp. 105-108.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**Date Submitted: June 23, 2006**

(use as many sheets as necessary)

Sheet	2	of	2
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Application Number	Unassigned
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<b>Filing Date</b>	June 23, 2006
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First Named Inventor	Nobuaki TAKAHASHI
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Examiner Name	Unassigned
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Attorney Docket Number	081356-0262
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Examiner  
: Initials\*Cite  
No.1

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

T6

Y. XU et al., "Residue at position 331 in the IgG1 and IgG4 CH2 domains contributes to their differential ability to bind and activate complement", 1994, J. Biol. Chem. 269(5), pp. 3469-3474.

M. H. TAO et al., "The differential ability of human IgG1 and IgG4 to activate complement is determined by the COOH-terminal sequence of the CH2 domain", 1991, J. Exp. Med., 173(4), pp. 1025-1028.

E.E. IDUSOGIE et al., "Engineered antibodies with increased activity to recruit complement", 2001, J. Immunol., 166(4), pp. 2571-2575.

R.C. AALBERSE et al., "IgG4 breaking the rules", 2002, Immunology 105(1), pp. 9-19.

R. NEWMAN et al., "Modification of the Fc Region of a Primatized IgG Antibody to Human CD4 Retains Its Ability to Modulate CD4 Receptors but Does Not Deplete CD4+ T Cells in Chimpanzees", 2001, *Clinical Immunology*, 98(2), pp. 164-174.

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